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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,160	03/10/2004	Franz-Josef Rubroeder	02481.1671-02000	2543

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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,160	RUBROEDER ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/10/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Claims 23-67 are pending and under examination.

Information Disclosure Statement

The Information Disclosure Statement (IDS) filed on 3/10/2004 has been considered.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. US 09/991,964, filed 11/26/2001. However, the prior application US 09/991,964 has been published and is now US Patent No. 6,734,164. Therefore, applicant needs to update the priority claim.

Claim Objections

Claims 25, 31, 32, 40, 50, 56, 57 and 65 are objected to because of the following informalities:

Claim 25, line 2 recites "protein prepared in a microorganism". Whereas, proteins, in general, are produced in an organism, and then prepared in a suitable buffer. Applicant is advised to replace "protein prepared in a microorganism" with "protein produced in an organism".

Claim 31, line 2 recites "protein prepared in an insect cell". Whereas, proteins are produced in an insect cell, and then prepared in a suitable buffer. Applicant is advised to replace "protein prepared in an insect cell" with "protein produced in an insect cell".

Claim 32, line 2 recites "prepared from an expression vector construct". Applicant is advised to replace "prepared from an expression vector construct" with "encoded by an expression vector".

Claim 40, line 2 recites " purification and isolation". Where the claimed protein has already been isolated (see claim 39). Applicant is advised to delete the word "isolation" or replace it with a more appropriate word to further limit the claim.

Claims 50, line 2 recites "protein prepared in a microorganism". Applicant is advised to replace it with "protein produced in an organism".

Claim 56, line 2 recites "protein prepared in an insect cell". Applicant is advised to replace "protein prepared in a microorganism" with "protein produced in an insect cell".

Claim 57, line 2 recites ""protein prepared in a microorganism". Applicant is advised to replace "protein prepared in a microorganism " with "encoded by en expression vector".

Claim 65, line 2 recites " purification and isolation". Where the claimed protein has already been isolated (see claim 64). Applicant is advised to delete the word isolation or replace it with a more appropriate word to further limit the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement

requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986).

Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The claims are drawn to a process for the storage of a protein in aqueous solution comprising adding an amount of cysteine effective to delay the temporal decrease in the effective concentration of the protein by preventing chemical modification of SH groups on the protein during storage.

Hayakawa et al (IDS, EP 0437622 A1) teach that a number of factors such as sugars, amino acids, inorganic salts, and proteins can be used to improve the stability of a protein. The phrase "preventing chemical modification of SH groups on the protein ", given its broadest reasonable interpretation with the specification, requires that absolutely no modification to any SH group of any protein during the entire storage period of the protein life. There is no evidence, either in the specification or in the prior art, that addition of cysteine would prevent SH group modification of any protein. The specification teaches that addition of cysteine to insulin in aqueous solution enhances the stability of the insulin protein during storage (Table 1-4, page 10-11), however there is no support for the prevention of -SH group modification, as is required by the claims,

and neither can such support be obtained through reasonable extrapolation of the data. Applicant is advised to replace the word "preventing" with reducing or inhibiting to overcome this rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23-67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6, 339,061. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is a process for the storage of a protein in aqueous solution comprising adding an amount of cysteine effective to delay the temporal decrease in the effective concentration of the protein by preventing chemical modification of SH groups on the protein during storage, wherein the effective concentration does not decrease by (i) more than about 7%, (ii) more than about 3%, wherein the protein is a heterologous protein prepared in a microorganism, wherein the protein is dissolved or in suspension, wherein the protein is stored at about 0°C to 50°C, wherein the protein is stored from greater than 24 hours to 2 months, and wherein the protein is human insulin, whereas claims 1-24 of U.S. Patent No. 6, 339,061 are drawn to for the storage of a protein in aqueous solution comprising adding cysteine to the aqueous solution in a concentration of from about 100 mM to delay the temporal decrease in the effective concentration of the protein. The instant invention does not require that the process of storing a protein have cysteine at a concentration of from about 100 mM but it would be obvious to try different concentrations to prolong the storage of a protein. Further, the instant claims require prevention of any –SH group modification during the storage of a protein. Therefore, the scope of the instant invention is different than the U.S Patent No. 6, 339,061.

Claims 23-67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6, 734,164. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is a process for the storage of a protein in aqueous solution comprising adding an amount of cysteine effective to delay the temporal decrease in the effective concentration of the protein by preventing chemical modification of SH groups on the protein during storage, wherein the effective concentration does not decrease by (i) more than about 7%, (ii) more than about 3%, wherein the protein is a heterologous protein prepared in a microorganism, wherein the protein is dissolved or in suspension, wherein the protein is stored at about 0°C to 50°C, wherein the protein is stored from greater than 24 hours to 2 months, and wherein the protein is human insulin, whereas claims 1 - 6 of U.S. Patent No. 6, 734,164 drawn to for the storage of a protein in aqueous solution comprising adding cysteine to the aqueous solution in a concentration of from about 100 mM to delay the temporal decrease in the effective concentration of the protein. The instant invention does not require that the process of storing a protein have cysteine at a concentration of from about 100 mM but it would be obvious to try different concentrations to prolong the storage of a protein. Further, the instant claims require prevention of any –SH group modification during the storage of a protein wherein the effective concentration does not decrease by more than about 3%. Therefore, the scope of the instant invention is different than the U.S Patent No. 6, 734,164.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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15 September 2006
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PRIMARY EXAMINER